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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	00952-8033	8881
90628 7590 05/09/2013 Massachusetts General Hospital The General Hospital Corporation Perkins Cole LLP 700 13th Street, NW, Suite 600 Washington, DC 20005-3960				
EXAMINER MCCLENDON, SANZA L				
ART UNIT		PAPER NUMBER		
1765				
NOTIFICATION DATE		DELIVERY MODE		
05/09/2013		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jisacson@perkinscoie.com
dmayhew@perkinscoie.com
patentprocurement@perkinscoie.com

Office Action Summary**Application No.**

09/764,445

Applicant(s)

MERRILL ET AL.

Examiner

SANZA MCCLENDON

Art Unit

1765

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2013.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-130 and 143-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-130, 143-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-5B/03)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 15, 2013 has been entered.

Response to Amendment

2. In response to the Amendment received on March 15, 2013, the examiner has carefully considered the amendments. The instantly filed application is now being examined by Sanza McClendon; please find all relevant contact information below.

Response to Arguments

3. The instantly claimed processes (claims 124, 125, 130,143 and 147) require (1) irradiating an UHMWPE fabricated article that was pre-heated to above the melting point prior to irradiation (2) heating the irradiated UHMWPE article to 150°C or above or above the melting point to crosslink the UHMWPE (3) cooling the crosslinked UHMWPE article and (4) forming an implant form the crosslinked UHMWPE a article. Sterilizing the implant is included in some claims. The instant product by process claims 126-127 rely upon the processes for patentability. Instant claims 128-129 rely upon the swell ratio and degree of oxidation properties for patentability of crosslinked UHMWPE and an implant comprising the crosslinked UHMWPE.

4. Applicant's arguments see Remarks/Amendment, filed March 15, 2013, with respect to claims 124-130 and 143-149 have been fully considered and are persuasive. The rejection of claims 124-130 and 143-149 under 35 USC 102(e) as being unpatentable over Shen et al (6,228,900) has been withdrawn. The rejection of claims 125-129 and 147 under 35 USC 102(e) as being unpatentable over

Hyon et al (6,168,626) has been withdrawn. The examiner deems the prior art, alone or in combination, fails to set forth a process including pre-heating UHMWPE above the melting point prior to irradiation of a prefabricated article comprising UHMWPE to form free radicals in said UHMWPE.

5. Applicant continues to argue that the instantly claimed process was disclosed by applicant in Application 08/600,744 to establish a prior filing date of 02-13-1996 for the instantly claimed process and products before the 07-09-1996 filing date of Shen et al (6,228,900) and/or the 05-06-1996 filing date of Hyon et al (6,168,626). These arguments are moot since applicant has overcome the rejections by amending the claims in the process to include preheating said UHMWPE above the melting point prior to the irradiation step.

6. With respect to the reduction to practice of the instantly claimed processes the examiner has familiarized her-self with the application history, including all Declarations and Arguments filed by applicant, as well as, all rejections and response to arguments mailed to applicant and weighed all the evidence in view of the instantly filed amendment. Because the prosecution history is dense and lengthy, the present examiner deems it is important to summarize in some detail the present examiners understanding of the differences in opinion held between Applicant and Examiner Berman before proceeding to articulate his own views of the merits of the amendment and arguments of both aforementioned parties.

7. Presently the claims are directed to a process for preparing a medical implant having improved wear properties and oxidation resistance, as well as, a crosslinked UHMWPE article obtained by a process including the steps of exposing of a once molten UMWPE to radiation and re-melting said irradiated UHMWPE, then allowing said re-melted UHMWPE to cool. Said "pre-melting (once molten) UHMWPE prior to irradiation" limitation appears to have been introduced as means of further differentiating the instant invention over the prior art, as well as, to further establish reduction to practice, which is presently the main point of contention since the prior art rejections have been withdraw for failing to explicitly teach and/or render obvious "pre-heating above the melting point prior to irradiation of the UHMWPE".

8. With respect to applicant's arguments regarding Saum et al (6,017,975) and its process, which applicant deems similar, if not the same, being patentable over the prior art at the time of its effective filing date, the examiner deems the examination and prosecution history of the Saum et al patent has no bearing or weight in the prosecution and examination of the instant application. Additionally, Saum

et al clearly sets forth annealing irradiated UHMWPE at a temperature above the melting point in the disclosure. The issue at hand in this instant applicant is when the instantly claimed invention was reduced to practice which is necessary to establish the effective filing date. Examiner Berman argues the effective filing date is based on priority application 08/726,313, which has a filing date of October 2, 1996, since said priority application disclosed a method where UHMWPE is melted and then irradiated, as well as, setting forth a method where the UHMWPE is irradiated and then melted. Applicants have respectfully disagreed stating that not all method in the specification require 'a melting' step, but, as a way to advance prosecution, have amended the instant claims to require said claims to have a melt-history prior to irradiation.

9. Applicant appears to be interpreting the instant method claims a reciting that the irradiated UHMWPE material is heated above the melting point and the starting UHMWPE material is also heated above the melting point prior to irradiation; which applicant believe proves the reduction to practice before 1/20/1995 since these limitations are found in view of the specification, as well as, the declaration of Merrill et al. This is the main point of contention between previous examiner Berman and the applicant's. The present examiner, as well as Examiner Berman, is interpreting the instantly written and presently amended claims, given its broadest and reasonable interpretation, as well as, in view of the definitions to a be method comprising irradiating UHMWPE which was pre-heated above the melting point at some time prior to irradiation (*since the claims are not specific to whether this is immediately prior to irradiation or at some timed during the polymerization process*), which after irradiation is re-melted at a temperature of 150 deg. C or above in a substantially oxygen-free atmosphere for a time to combine all free radicals, allowed to cool and then further processed by forming and sterilizing. It appears both parties agree on the interpretation of the instantly written claims; however the point of contention between all parties appears to be if this method is found in the originally filed disclosure of the grandparent application, 08/600,744, having an effective filing date of October 02, 1996.

10. Applicant continually argue Example 6 in Application 08/600,744 supports the instantly amended and written claims: The examiner agrees with applicant that Examiner Berman agrees the UHMWPE sample was heated above the melting point (molten) and that an electron beam was irradiated into the chamber through a thin foil at the top, such that a maximum dose of 20 Mrad was received 5 mm below the surface of the polymer. Yes it is agreed upon that Ex. Berman accepted the

irradiation was done using a van de Graaff generator with electron energy of 2.5 MeV and a dose rate of 1.67 Mrad/min, the heating was stopped and the sample allowed to cool to room temperature after irradiation stopped. Regarding the argument and statements regarding Example 6 being silent with regard placing the chamber on a conveyor belt or moving the chamber on a conveyor belt during the irradiation are acknowledged and deemed unnecessary at this point in the response since they are not claim limitations but may be discussed at some further point in this response. Examiner Berman argues example 6 does not suggest a process starting with irradiation to form free radicals and followed by heating to 150 deg. or above after irradiation to form crosslinks before cooling. The present examiner is inclined to agree. There is nothing in example 1, 3 or 6 (all methods of pre-heating above the melting point prior to irradiation) of 08/400,744 to suggest at the point when irradiation is stopped the sample was heated to 150 OC or above until all the radical recombined before cooling. The example states heating above the melting point and holding this temperature for 30 min. prior to irradiation (pre-heat step/prior melt history), irradiating using a van de Graaff generator with electron energy of 2.5 MeV at a dose rate of 1.67 MRad/min until a maximum dose of 20 MRads was obtained and after irradiation the heating was stopped and the sample was allowed to cool to room temperature at a rate of 0.5 deg. C/min. The present examiner agrees the formation of free radical is inherent to the exposure to electron beams since electron beams supply enough energy to break a carbon-carbon bond. It is agreed upon the examiner Berman has acknowledged that UHMWPE was heat (melted), which does mean the heating temperature was above the melting point. However the present examiner does not agree Examiner Berman has agreed the step of heating above 150 deg. C after irradiation is within the scope of the disclosure. From the overall prosecution history it is clear examiner Berman does not find a teaching that the irradiated UHMWPE **was heated** 150 OC or above **after** irradiation, as the claim is written. For this reason applicants have submitted a declaration by Dr. Muratoglu, filed herein on 11/9/20092 but originally filed in application 11/184,803 a related application, to show one skilled in the art would appreciate that the process of using van de Graaff generator involves a step by step process of irradiation, heating , and cooling. In said declaration Mr. Muratoglu reviewed Exhibit 3 which shows that Experiment 2 describes a step by step process of heating and continued irradiation and heating



which is reproduced as:

From this

applicant's assert, as well as, Dr. Muratoglu et al, that said sketch involves process of "repeated heating and radiation" and the crosslinked material can be cooled after a desired radiation dose is received. The present examiner agrees the declaration, as well as, the sketch shows a method of pre-heating and steps of repeated irradiation and heat (intermittent heating—taken from example 2 in Exhibit 3. However, while the examiner does agree with the assessment as outlined in the Muratoglu declaration as to the matter of how UHMWPE in example 2 (similar to example 6 of 08/600,744) is treated/processed using the van de Graaff device; this assessment is not commensurate in scope with the claims and/or the experiment 2 in the declaration is not commensurate in scope with the claims. The sketch from the Muratoglu declaration sets forth a method wherein polyethylene is melted (pre-heat according to the claim) and repeatedly irradiated and heated until the desired dose is obtained, i.e., "a step by step process of irradiation, pause of cease in between passes, heating during the cease or pause in-between, and repeating until the desired dose of radiation is obtained"—paragraphs 4 and 5 of the Muratoglu declaration. The declaration of Merrill et al, filed 11/19/2009, specifically states "the samples here heated to melt and irradiated in the molten state" in paragraph 6. These statements are not commensurate in scope with the instantly written claims. Instantly written claim 24 require these steps (1) pre-heating above the melting point (molten state) prior to irradiation, (2) irradiated for form free radicals, (3) heating after irradiation in an substantially oxygen-free atmosphere to 150 deg. C or above; (4) cooling while maintaining a substantially oxygen-free atmosphere; (4) forming a medical implant and (5) sterilizing. Instant claim 125, requires the steps of (1) pre-heating above the melting point (molten state) prior to irradiation, (2) irradiated for form free radicals, (3) heating after irradiation in an substantially oxygen-free atmosphere to 150 deg. C or above; (4) cooling while maintaining a substantially oxygen-free atmosphere; (4) forming a medical implant. Instantly written claim 130 requires the steps of (1) pre-heating above the melting point (molten state) prior to irradiation, (2) irradiated for form free radicals, (3) heating after irradiation in an substantially oxygen-free atmosphere to 150 deg. C or above; (4) cooling while maintaining a substantially oxygen-free atmosphere; (4) forming a medical implant; and (5) sterilizing. Instant claim 143 requires the steps of (1) pre-heating

above the melting point (molten state) prior to irradiation, (2) irradiated for form free radicals, (3) heating after irradiation to a temperature above the melting point; (4) cooling while maintaining a substantially oxygen-free atmosphere; (4) forming a medical implant; and (5) sterilizing. Instant claim 147 requires the steps of (1) pre-heating above the melting point (molten state) prior to irradiation, (2) irradiated for form free radicals, (3) melting, after irradiation; and (4) cooling. These claimed steps, even given their broadest interpretation, do not set forth the steps of "repeated heating and radiation", as suggested by Muratoglu et al, nor do they set forth the steps of "irradiating in the molten state". From the examiner's standpoint the broadest and most reasonable interpretation of the instant claims would be the steps of (1) pre-heating to the UHMWPE above the melting point to render molten, (2) irradiating the molten UHMWPE to produce free radicals (at what point this beings to happen is not found in the claim or is it possible to infer from the claims or the teachings of the instant disclosure or the originally filed grandparent disclosure), (2) placing in a substantially oxygen free atmosphere and heating again above the melting point for a time sufficient to recombined substantially all the free radicals produced in step (2) thus thereby crosslinking said UHMWPE; (4) cooling the heated (molten) crosslinked the article of step (3) and then sterilizing. It is not possible to infer and/or read into the claim repeated steps of irradiating in the molten state since there is no requirement in the step (1) that the pre-heated polyethylene be in the molten state immediately before irradiation only that at some point prior to irradiation that the polyethylene be heat above the melting point, which given its broadest and most reasonable expectation, could be any time after polymerization of ethylene up until the point of irradiating it. Additionally because the second heat step (after the irradiation step) requires the irradiated polyethylene to be in a substantially oxygen free atmosphere and the irradiation step does not required to be in a substantially oxygen free atmosphere one can infer/interpret from the claim, as instantly written, that these are two different steps, i.e., wherein irradiating is step (2) and placing in an oxygen free atmosphere prior and heating would be step (3). It is possible to infer/interpret from the claim that the process as instantly written applicant intends to either "cease and/or pause with heating" in between irradiation steps until free radicals are formed or that UHMWPE is to be "irradiated in the molten state". Therefore it is deemed the van de Graaff generator used in example 6 of co-pending 08/600,744, as well as, explained in the arguments and numerous declarations, does not inherently disclose the process as instantly claimed. As too the inherency arguments that the discussed generators inherently describes the process, the examiner is weary to agree since as stated by applicant not all

embodiments in the disclosure requires a pre-heating step that heats above the melting point and all embodiments regardless of pre-heating or not, use a van der Graaff generator to crosslink UHWMPE, i.e., CIR-SM and WIR-AM both found in the instant disclosure. Additionally, from example 6 it can be seen that the heating can be started and stopped without the need to manipulate/use the electron beam radiation exposure step, evidenced by the fact that heating was started, held for 30 min, to obtain the molten state, the pre-heated (not required to be molten in the claim) is then irradiated, the irradiation is stop and then the heat is stopped; therefore the heating and irradiation can be manipulated differently not necessarily manipulated at the same time. This also evidenced by the sketch since it appears the process can be stopped right after the first irradiation step since there is no time requirement or stipulation when free radicals form. To believe/accept the generator inherently functions the way applicants state would mean the CIR-SM method (cold irradiation and subsequent melting) is not truly cold irradiated (i.e., irradiated at room temperature) but instead pre-heated and irradiation and subsequently heated again repeatedly until the process obtains the desired product. It appears applicant is relying upon a partial sequence that might be inherent to use of a van der Graaff generator for irradiation but ignores the disclosure that Example 6 is a process wherein the process required heating of the polyethylene sample followed by irradiation until the maximum dose was reached and then followed by cooling to room temperature. Therefore, applicant's argument that use of a van der Graaff generator in Example 6 inherently discloses the instantly recited process steps is not persuasive to establish an effective filing date of 02-13-1996 for the instant claims. The only inherency the present examiner sees in relation to the instant claims is the generator once turned on forms free radicals in the polyethylene. The instantly claimed process steps are required to be in order of irradiating pre-heated UHMWPE, then heating and then cooling while the process steps in disclosed in 08/600,744 Example 6 are required to be in the order heating, then irradiating and then cooling.

11. Regarding arguments to the Declaration of Merrill et al filed 11-19-2009: Applicant's arguments that the evidence presented in the Rule 1.131 Declaration of Merrill et al filed 11-19-2009 shows reduction to practice before January 20, 1995 is unpersuasive for reasons of record, Applicants point to sections 5 and 10 of the Declaration for evidence of conception and reduction to practice of the instantly recited method steps before January 20, 1995. Item b) of Exhibit 1 referred to in sections 5 and 10 of the Declaration discloses the concept of irradiation at room temperature to increase crosslinking in the amorphous zones and states that melting and recrystallizing will *"probably again lead to the*

original crystal structure...and selective segregation of crosslinks into the amorphous regions". However, this statement of basic motivation does not state subsequent melting was part of the process for crosslinking or provide evidence reduction to practice. Exhibit 3, Experiment 1, referred to in sections 12-14 of the Declaration discloses irradiation of solid UPE followed by DSC runs in set 2. ***The DSC thermal testing was carried out, according to Exhibit 3, Experiment 1, dated before 01-25-1995, to determine crystallinity levels of the irradiated UPE, not as a CIR-SM method to crosslink irradiated UHMWPE, as set forth in the instant claims and argued in the Declaration.*** The Examiner's position, as previously stated, is that the DSC thermal analysis method for determining the melting and crystallization temperatures of irradiated UHMWPE by thermal analysis cannot be relied upon as evidence of reduction to practice of the process set forth in the instant claims. *DSC thermal analysis is disclosed as a method of testing for melting and crystallization temperatures, not a method of treating irradiated UHMWPE to crosslink the irradiated UHMWPE.* The instant claims recite irradiation of pre-heated UHMWPE to form free radicals followed by heating/melting to crosslink the UHMWPE, not melting and recrystallizing to determine melting and recrystallization temperatures. Thus, evidence of DSC thermal analysis is not considered evidence of reduction to practice of the instantly claimed process before January 20, 1995, as alleged by applicant. Section 10 is cited for the statement that another "embodiment...to solve the wear problem" involved crosslinking polyethylene at room temperature by irradiation and subsequent melting, i.e., the "CIR-SM" process disclosed in Application 08/726,313, filed 10-02-1996. With respect to claims 128-129, the swell ratios reported in the Exhibit 6 are obtained by the method of melt-irradiation of UHMWPE.

12. Regarding the Declaration of Orhun K. Muratoglu filed 11-19-2009: Applicant argues that Dr. Muratoglu points to Exhibit 3, Experiment 2, in the Declaration of Merrill et al as evidence of reduction to practice of the instantly claimed process. Experiment 2 is said to provide evidence of a process requiring repeated steps of heating and irradiating consolidated polymer using a van der Graaff generator. This evidence is not persuasive for the following reasons. Experiment 2 discloses a process wherein UPE barstock is heated to 175°C, then irradiated to 1.0 Mrad followed by repeating the steps of heating and irradiating to a final step of irradiation to provide a total dose of 50 Mrad. The samples were evidently then analyzed using the DSC thermal testing. *This experiment does not provide evidence of reduction to practice of the instantly claimed process, which requires irradiation of a fabricated article of UHMWPE to form free radicals, followed by heating the irradiated article in an oxygen-free atmosphere*

to a temperature of 150°C or greater to crosslink the irradiated UHMWPE, followed by cooling. Specifically, the instantly claimed process does not include heating to a temperature above 150°C before irradiation, multiple heating and irradiation steps and an irradiation step before the cooling step. The disclosure of heating after irradiation as part of a continuous process of heating and irradiating starting with heating and ending with irradiating is not considered to be a reduction to practice of the instantly claimed method.

13. Regarding inherency of process steps when using a van der Graaff generator presented to establish an effective filing date of 02-13-1996. The relevant passage in the MPEP with respect to inherent functions or properties in a disclosure is as follows: “To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient”. In the instant case, the mere fact that the Van de Graaff generator was used in Example 6 of 08/600,744 is not sufficient to establish that process steps in the order set forth in the instant claims were employed in Example 6.

MPEP §2163.07(a): the cited MPEP section states that an application may be amended to recite a function, theory or advantage of a device that inherently performs a function, operates according to a theory or has an advantage without introducing new matter. Thus applicant may amend the specification to include a known function of the Van de Graaff generator. However, this section of the MPEP does not suggest amending the specification to introduce a method employing the known function that is materially different from the method that was originally disclosed.

14. Product claims 128-129: Example 4 discloses swell ratio for melt-irradiated UHMWPE (GUR 415) from the grandparent 08/600,744, i.e. UHMWPE that was melted and then irradiated while molten (Example 2). Degree of oxidation at a given depth of crosslinked UHMWPE is not mentioned. Example 11, Tables 8 and 11 are not disclosed in 08/600744. The instant claims 128-129 recite that the method is to irradiate UHMWPE, melt the irradiated UHMWPE and cool the UHMWPE, i.e. the claims do not recite irradiating UHMWPE in the melt, as disclosed in 08/600,744.

Claim Interpretation and Effective Filing Date

15. Claims 124-127, 130 and 143-149, recite a process wherein irradiation of preheated UHMWPE to form free radicals is subsequently followed by heating or melting to crosslink the UHMWPE: a method ("WIR-AM) first disclosed in SN 08/726,313, filed 10-02-1996. Additionally, the present examiner deems from the overall teachings in the disclosure of 08/726,313 sets forth in one embodiment preheating above the melting point prior to irradiation UHMWPE to form free radicals, wherein from the overall teachings one of ordinary skill in the art could infer/obtain heating the irradiated UHMWPE to quench all free radicals. This teaching can be inferred from the disclosure where it is set forth the use of gamma radiation in the irradiation method "...gives high penetration depth but takes a longer time, resulting in the possibility of some oxidation" and that the use of electron beam "...more limited penetration depths but takes a shorter time, and hence the possibility of oxidation is reduced", wherein from the disclosure it is known that if not recombined the free radicals formed from the irradiation step will oxidize in air, wherein the disclosure solves the problem of oxidation by heating the irradiated UHMWPE above the melting point to recombine substantially all free radicals. Taking these teachings into consideration it is deemed one of ordinary skill in the art would understand from the overall teachings of the disclosure that the irradiation of the polyethylene forms free radicals and that heating the irradiated polyethylene will recombine all the free radicals to prevent oxidation which is deemed an unwanted property in medical implants. It is deemed that if the examiner was presented with a claim (in a different application) requiring the step of subsequent melting of irradiated polyethylene these teachings from the instant disclosure would be applied as rendering the claim (in said different application) obvious. These specific teaching are found in the disclosure of application serial number 08/726,313; however, these same teachings, specifically the method of solving the oxidation problem by re-melting the irradiated UHMWPE are not disclosed or set forth in serial number 08/400,744 in a reasonable manner as to render then obvious as found in the disclosure of 08/726,313. Therefore the examiner deems the effective filing date of the instantly written and claimed invention of claims 124-27, 128, and 143-174 is 10/02/1996.

16. Claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN '744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN '744. SN '313 does disclose the swell ratio or degree of oxidation of the disclosed UHMWPE, therefore, the effective filing date for claims 128-129 is considered to be 10/02/1996.

17. The reasons why the statements and data in the Declarations of Merrill et al and Muratoglu, of record, do not establish reduction to practice of the processes and products as instantly claimed are discussed herein above.

18. **The rejections as recited above have been withdrawn for the reasons discussed above. However, upon further consideration, a new ground(s) of rejection is made in view of Muratoglu et al (2007/0265369, effective filing date February 03, 2004).** Regarding the double patenting rejections, the examiner deems since these are not the only remaining claims in the instant application and all co-pending applications set the in the teachings preheating above the melting point, irradiating to form free radicals, heating above the melting point, cooling and sterilizing, it is considered It is deemed that the instant claims, as written, cannot be infringed without literally infringing upon the claim/definitions of the co-pending application(s) as cited in the obviousness-type double patenting rejection(s). Applicant's attention is drawn to MPEP 804 where it is disclosed that "the specification can always be used as a dictionary to learn the meaning of terms in a patent claim." *In re Boylan*, 392 F.2d 1014, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in an application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F/2d 438,164 USPQ 619,622 (CCPA 1970). Please find all rejections below.

Claim Rejections - 35 USC § 102/35 USC § 103

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 124-130, and 143 to 149 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muratoglu et al (2007/0267030).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

22. Muratoglu et al explicitly sets forth in example 13, irradiating UHMWPE, that has been compression molded by heating to 180 deg. C with pressure, using electron beam irradiation using a 2.5 MeV van de Graaff generator to 150 kGy at room temperature and then a section of said irradiated UHMWPE is by heating to a temperature of 170 deg. C in a vacuum (i.e. a substantially oxygen free atmosphere). The examiner deems this anticipates steps (1) to (3) of instant claims **124, 125, 130, 143 and 147** wherein the compression molding step anticipates the pre-heating above the melting point of UHMWPE, since the claims are written read on both irradiating immediately after preheating above the melting point, as well as, and point prior to irradiation, such as during the stock production, such forming bars and rods by compression molding as taught in the cited reference. This method is deemed to anticipate the articles of instant **claims 126-127**. The primary difference between the instantly written invention and example 13 is example 13 does not explicitly set forth the step of cooling while maintaining in a substantially oxygen-free atmosphere, the step of forming a medical implant and the step of sterilizing as required in instant claims **124, 130, 143, and 147**. However, as can be seen from the overall teachings of the reference said annealed crosslinked article is then cooled, machined to form

medical implants and sterilized--see [0035]. Thus it is deemed one of ordinary skill in the art would have found it obvious, at the time of the invention, to cool the annealed above the melting point crosslinked UHMWPE, machining said cooled article to form a medical implant and sterilizing from the overall teachings of the reference. Muratoglu et al sets forth said sterilization methods can be done using gamma or electron beam radiation or gas methods, such as by exposure to ethylene oxide gas, wherein said radiation is applied at higher level than used in the irradiation process to form the free radicals, such as from 25 to 200 kGy. the examiner deems the use of such high levels of radiation would inherently produce heat and thus heat can be considered as part of this sterilization method, and thusly rendering claims 144-146 obvious in view of the teachings of Muratoglu et al in absence of evidence to the contrary and/or unexpected results.

23. Regarding the product by process claims of instant claims 128-129: it is deemed Muratoglu et al sets forth the instantly claimed method in the overall teachings and in example 13, wherein it is additionally deemed the annealed sample of example 13 would have to be cool to room temperature in order to further process and/or use said crosslinked article in the defined utility, and therefore in absence of evidence to the contrary and/or unexpected results it is deemed the products obtained by the Muratoglu et al method would inherently having the claimed swell ratio and degree of oxidation at the claimed depths of instant claim 128.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. P00Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. **Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. **Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 127 and 136 of copending Application No. 10/197209.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. **Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. It

would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. **Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 125, 129, 130, 132-134, 136, 138, and 145-152 of copending Application No. 10/197263.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SANZA MCCLENDON whose telephone number is (571)272-1074. The examiner can normally be reached on Monday through Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sanza L McClendon/
Primary Examiner, Art Unit 1765

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